

REMARKS

This is a full and timely response to the final Official Action mailed **August 14, 2008** (the “Office Action” or “Action”). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Request for Continued Examination (RCE):

Applicant hereby requests Continued Examination for this application and entry and consideration of this amendment consequent thereto.

Claim Status:

Under the imposition of a previous Restriction Requirement, claims 6, 17-54 and 57-59 were withdrawn. To expedite the prosecution of this application, withdrawn claims 21-54 and 57-59 are cancelled by the present paper without prejudice or disclaimer. Applicant reserves the right to file continuation or divisional applications as permitted by 37 C.F.R. to the withdrawn claims or to any other subject matter described in the present application.

The other withdrawn claims depend from elected claim 1 and remain in the application. Applicant will be entitled to rejoinder of those claims upon allowance of claim

1. MPEP § 821.04

By the present paper, claims 2, 14, 55, 56 and 60-62 have been cancelled without prejudice or disclaimer. Various claims have been amended. No new claims are added. Thus, claims 1, 3-5, 7-13, 15, 16 and 63-67 are currently pending for further action.

35 U.S.C. § 112, first paragraph:

In the recent Office Action, claims 1-5, 8-16 and 20-62 were rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled by the specification. While Applicant does not necessarily agree that any of these claims were non-enabled, the indicated claims have been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, first paragraph. Following this amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

35 U.S.C. § 112, second paragraph:

In the recent Office Action, claims 5, 55-56 and 63-67 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. While Applicant does not necessarily agree that any of these claims were indefinite, the indicated claims have been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, second paragraph. Following this amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Prior Art:

The recent Office Action makes four alternative rejections, each of which apply to independent claim 1. The four grounds of rejection are as follows.

(1) Claims 1-5, 7, 8, 10-15, 60 and 61 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,653,996 to Hsu (“Hsu”).

(2) Claims 1-5, 7-15, 60 and 61 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,976,964 to Schlossmann (“Schlossmann”).

(3) Claims 1-3, 5, 7, 8, 12-15 and 60-61 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,958,378 to Waldrep (“Waldrep”).

(4) Claims 1-5, 7, 8, 10-12, 14-15, 55-56, 63 and 64 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,160,669 to Wallach (“Wallach”).

For at least the following reasons, these rejections should now be reconsidered and withdrawn.

Independent claim 1 now recites:

A jettable solution comprising:
a plurality of vesicles;
a pharmaceutical payload encapsulated within each of said vesicles; and
an edible liquid vehicle, said plurality of vesicles being stably dispersed in said edible vehicle;
wherein said jettable solution is jettable with an inkjet material dispenser to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

Support for the amendment to claim 1 can be found in Applicant’s originally filed specification at, for example, claims 2 and 14 and paragraphs 0015 and 0049. Applicant notes that claim 1 now expressly recites that the claimed “jettable solution is jettable with an inkjet material dispenser to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.”

As would be known of to one of skill in the art, and as explained in Applicant’s specification, at paragraph 0049 and elsewhere, in order to be jettable, a composition must have characteristics that will allow it to be delivered given the pressures, temperatures and other parameters of an inkjet material dispenser while protecting the pharmaceutical payload. For example, for a solution to be “jettable” it must have a certain viscosity, surface tension, density, and T-cycle stability. (*See e.g.*, Applicant’s specification, paragraphs 0049, 0059).

Whether or not the claimed solution is “jettable” is of immense significance.

Specifically, as described in Applicant’s specification,

The precise metering capability of the inkjet material dispenser (150) along with the ability to selectively emit the metered quantity of aqueous vesicle pharmaceutical (160) onto precise, digitally addressed locations makes the present system and method well suited for a number of pharmaceutical delivery applications. According to one exemplary embodiment, the precision and addressable dispensing provided by the present inkjet material dispenser (150) allows for one or more compositions to be dispensed on a single edible structure (170). According to this exemplary embodiment, a combination therapy may be produced in a customized dosage for a patient.

(Applicant’s specification, paragraph 0054).

Thus, with the claimed jettable composition, a prescribing physician can order “a customized dosage for a patient” that is then produced by a pharmacist with an inkjet material dispenser, similar to an inkjet printer. (*Id.*). Without, the jettable solution of Applicant’s invention, producing a customized dosage for each patient would be unreasonably expensive.

(Applicant’s specification, paragraph 0059). Consequently, the patient may have to ingest a much larger, standardized dosage of a pharmaceutical than the patient actually needs.

In contrast to the claimed subject matter, none of the cited prior art references teach or suggest the claimed “jettable solution.” Specifically, none of the cited references teach or suggest the claimed combination of a pharmaceutical payload encapsulated within each of a plurality of vesicles; and an edible liquid vehicle in which the vesicles are stably dispersed, “wherein said jettable solution is jettable with an inkjet material dispenser to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.” This subject matter and its advantages are entirely outside the scope and content of the cited prior art.

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed.

Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection of Applicant's claims based on any of Hsu, Schlossmann, Waldrep and Wallach should be reconsidered and withdrawn.

Claim 7 recites:

A jettable solution comprising:
a plurality of vesicles; and
a pharmaceutical payload encapsulated within a central interior of each of said vesicles;
wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is entrapped between said two layers of molecules of said vesicle outer membrane;
wherein said jettable solution is jettable with an inkjet material dispenser to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload.

Claim 7 should be considered allowable for at least the same reasons given above in favor of claim 1. Moreover, the final Office Action fails to specifically address claim 7 or to indicate how or where the cited prior art teaches the specific subject matter of claim 7. For at least these reasons, the rejection of claim 7 should be reconsidered and withdrawn.

Claim 16 was rejected under 35 U.S.C. §103(a) over any one of Hsu, Schlossmann or Waldrep taken individually. For at least the following reasons, this rejection cannot be sustained.

Claim 16 recites:

The jettable solution of claim 1, further comprising:
approximately 25 % vehicle;
approximately 2 % vesicle forming component;
approximately 3 to 6 % pharmaceutical payload; and
water.

As already demonstrated above, the composition and "jettability" of the claimed solution are significant to the advantages obtained by Applicant's discovery.

According to the Action, “[i]t is unclear from these [prior art] references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload. Assuming the amounts are different, it is deemed obvious to one of ordinary skill in the art to use desired amounts.” (Action, p. 7). This is an insufficient analysis on which to reject claim 16 under prevailing case law.

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007):

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, “[a]ll claim limitations must be considered” because “all words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385.

With regard to claim 16, the Office Action fails to determine the exact scope and content of the cited prior art and the differences between the cited prior art and the claimed subject matter. Rather, the Action finds it “unclear” whether the elements of the claimed composition is taught by the prior art. (Action, p. 7). Nevertheless, the Action, without supporting evidence, makes the conclusory statement that the claimed composition would be obvious.

In a recent decision, the Board of Patent Appeals and Interferences stated the following:

The Examiner's articulated reasoning . . . in the rejection must possess a rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The Supreme Court, reiterating this reasoning by citing *In re Kahn*, 441 F.3d at 988, stating that '*rejections on obviousness grounds cannot be sustained by mere conclusory statements*'; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.' *KSR* at 1741.

Ex Parte Val Mandrusou, Application Serial No. 10/235,221, 2008 WL 2845083 (B.P.A.I. 2008) (emphasis added).

For at least these reasons, the rejection of claim 16 is clearly insufficient and should not be sustained.

Claim 65 was rejected under 35 U.S.C. §03(a) over the combined teachings of Wallach and U.S. Patent No. 4,608,211 to Handjani. For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 65 now recites: "The jettable solution of claim 1, further comprising an antifoaming agent to prevent foaming of said solution." Support for the amendment to claim 65 can be found in Applicant's originally filed specification at, for example, paragraph 0033.

In contrast, neither Wallach nor Handjani teach or suggest a composition with an antifoaming agent that is effective "to prevent foaming of said solution." According to the Action, Handjani teaches "the routine practice of adding an antifoaming agent in liposomal compositions (col. 4, lines 1-15)." (Action, p. 8). What Handjani actually teaches is that "an anti-foaming agent is introduced into the aqueous phase *to be encapsulated*." (Handjani, col. 4, lines 1-15). Thus, Handjani teaches an antifoaming agent encapsulated in liposomal vesicles. Being encapsulated, the antifoaming agent cannot be effective "to prevent foaming

of said solution” as claimed. Thus, none of the cited prior art references teach or suggest the claimed jettable solution comprising an antifoaming agent effective to “prevent foaming of said solution.”

As noted above, under the analysis required by *Graham v. John Deere*, 383 U.S. 1 (1966) to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Wallach and Handjani, did not include the claimed subject matter, particularly an antifoaming agent to prevent foaming of said solution.

The differences between the cited prior art and the claimed subject matter are significant because the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 65 under 35 U.S.C. § 103 and *Graham*.

Claims 66 and 67 were allegedly rejected under 35 U.S.C. §103(a) over the combined teachings of Wallach and Schlossmann. However, the text of the rejection refers to Handjani which was not applied. The Action argues that “Handjani shoes the routine practice of adding buffers and glycerol in liposomal compositions.” (Action, p. 8). However, Applicant can find no such teachings in Handjani. Therefore, the rejection of these claims should be clarified or withdrawn.

Conclusion:

In view of the foregoing arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue or comment in the Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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